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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/997,490	11/17/2001	George Kindness		7843

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EXAMINER

COOK, REBECCA

ART UNIT PAPER NUMBER

1614

DATE MAILED: 05/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/997,490	KINDNESS ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Rebecca Cook	1614	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 26 September 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) 17-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 and 26-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

Applicants are requested to clarify the filing date of 60/245,592, since the filing date of 11/3/2000 is non consistent with PTO records.

Applicants request to amend claims 11, 12 and 13 could not be entered.

### ***Election/Restrictions***

Applicant's election with traverse of celecoxib and atorvastatin in Paper dated 9/26/03 is acknowledged. The traversal is on the ground(s) that statins and COX-2 inhibitors are similarly acting compounds and are generally interchangeable. This is not found persuasive. A reference citing one 3-HMG COA reductase inhibitors or COX-2 inhibitors cannot be used against all 3-HMG COA reductase inhibitors or COX-2 inhibitor, respectively.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-16 and 26-34 are being examined to the extent that they read on the elected compounds. Claims 17-25 are withdrawn as not reading on the elected compounds.

### **OBJECTION**

Claims 7-10 are objected to as improperly incorporating method steps into product claims. (MPEP 2116.01)

***Claim Rejections - 35 USC § 112***

Claims 1-16, 26-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1, 2, 4, 6 and 14 the intent of the word "initially" is confusing. It is unclear whether other therapeutic changes are also expected.

In claims 4, 6, 9, 10, 15 and 30 the recitation "in at least one of said at least one carrier" is not understood.

In claims 12-13 and 33-34 it is not clear what the recitation "at least one dietary supplement to maintain adequate levels of Vitamin C, Vitamin E and Selenium means. Is the intent to claim Vitamin C, Vitamin E and selenium, or does the dietary supplement contain other compounds?

The intent of the phrase "prophylactically effective amount" in the claims is confusing as to whether the intended use of the composition is to prevent or treat cancer, since the claims recite "treating" and "progression of cancer."

In claim 14 no administration step to an intended subject is recited. Furthermore, it is not clear what the intent is of the recitation "a therapeutically effective change in progression of cancer." Does it mean to prevent metastasis, shrink a tumor? It is not seen that the recitation is defined in the specification.

There is no formulation step in the method of manufacture of claims 29-34. The claims recite "incorporating in," but it is not clear what is incorporated into what.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 7, 8 and 29-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over 6,245,797 (Winokur).

Winokur (claims 46-49, claim 51-53, column 14, lines 55-56, column 23, lines 7-13) discloses a composition comprising an HMG-CoA reductase inhibitor and a COX-2 inhibitor and a method of combining the two inhibitors with a carrier. It further discloses that the HMG-CoA reductase inhibitor can be atorvastatin and the COX-2 inhibitor can be celecoxib. In the absence of a showing of unexpected results no obviousness is seen in combining two compounds, the combination of which is taught in the prior art.

Claims 1-10, 14-16 and 29-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over 6,492,410 (Leopold) and MEDLINE AN 2001153392 (Gately) in view of 5,817,695 (Pellico).

Leopold discloses (column 3, lines 39-55, column 19, lines 33-36, column 20) that HMG CoA reductase inhibitors, including atorvastatin, are useful to treat cancer. Gately (abstract) discloses that COX-2 inhibitors are useful to treat cancer. Gately does not recite celecoxib, but applicants states in the Paper received 11/5/03 on page 2 that COX-2 inhibitors are generally interchangeable. Therefore, in the absence of a showing

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of unexpected results it would be obvious to one of ordinary skill in the art to combine atorvastatin and celecoxib to yield the instant composition and use it to treat cancer.

Several of the claims recite a glutathione pathway enhancing and detoxifying compound that can be cystine. However, Pellico (examples) discloses that cystine is used in compositions given to people having cancer. It would be obvious to one of ordinary skill in the art to add the cystine of Pellico to yield the instant composition comprising atorvastatin, celecoxib and cystine and use it to treat cancer, since each is taught to be used for the same condition. It would be inherent that it would have the recited properties of the claims (MPEP 2112.01).

Claims 29-31 differ over the references in reciting a method of manufacturing an anti-cancer combination comprising atorvastatin and celecoxib, with or without cystine. However, no unobviousness is seen in combining the compounds to yield a composition, since combining compounds useful to treat the same condition is well-known in the pharmaceutical art. Pellico (column 8, examples) and Leopold (column 14, lines 13-23) disclose mixing compounds useful to treat cancer.

Claims 11-13, 26-28 and 32-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over 6,492,410 (Leopold) and MEDLINE AN 2001153392 (Gately) in view of 5,817,695 (Pellico) as applied to claims 1-10, 14-16 and 29-31 above, and further in view of 6,630,157 (Horrobin), MEDLINE AN 20001266354 (Khuri) and CA134:146792 (Padayatty).

The claims recite that the composition contains lipoic acid, Vitamin C, Vitamin E and selenium. However, Horrobin (column 5) discloses that lipoic acid is used to treat

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cancer; Padayatty (abstract) discloses that vitamin C is used to treat cancer and Khuri (abstract) discloses that vitamin E and selenium are useful to treat cancer. Therefore, it would be obvious to add lipoic acid, Vitamin C, Vitamin E and selenium to the composition comprising atorvastatin and celecoxib, with or without cystine, to yield the instant composition and use it to treat cancer, since each is taught in the art to be useful to treat cancer.

Additionally, no unobviousness is seen in combining the compounds to manufacture the anti-cancer combination for the reasons given above.

It is noted that MEDLINE AN 2001153392 and CA134:146792 issued in 2000. However, based on their issue number, it appears that they predate the instant priority date. The Examiner has ordered this information, which will be provided in the next Office Action.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Cook whose telephone number is (571) 272-0571. The examiner can normally be reached on Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (571) 272-0584.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Renee Pettus (571) 272-0547 in Customer Service.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Rebecca Cook

A handwritten signature in cursive script, appearing to read "Rebecca Cook".

Primary Examiner

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April 29, 2004